Maryland Board of Pharmacy Public Meeting MINUTES May 19, 2010

Today's Attendance Year-to-Date Attendance Name Title Present Absent Present Absent 10 Anderson, C. Commissioner Χ 1 Bradley-Baker, L. Х 11 0 Commissioner Chason, D. Commissioner Х 11 0 Finke, H. Х 10 1 Commissioner Handelman, M. Commissioner Х 10 Israbian-Jamgochian, L. Commissioner Χ 0 11 Leandre, A. Χ 10 1 Commissioner Matens, R. Х 9 2 Commissioner Souranis, M. Commissioner/Treasurer Х 9 2 Х 0 Taylor, D. Commissioner/President 11 Taylor, R. Commissioner/Secretary Х 10 1 Zimmer, R. Commissioner Х 10 1 **Board Counsel** Bethman, L. Χ 11 0 Gibbs, F. **Board Counsel** Х 11 0 Χ Banks, T. MIS Manager 6 5 Gaither, P. Administration and Public Support Manager Χ 11 0 Х Goodman, S. Licensing Manager 7 4 Legislation/Regulations Manager Jeffers, A. Χ 0 11 Naesea, L. **Executive Director** X 11 0 Waddell, L. **Executive Secretary** 9 2 Х France, K Compliance Officer 2 X 1 Seeds, J PIO 3 0

Subject	Responsible		Motion	ACTION/RESULTS
	Party	Discussion		
I. Call to Order & Approval of Minutes	Donald Taylor, Board President	 A. D. Taylor called the Public Meeting to order at 9:00am. B. D. Taylor requested all meeting attendees to introduce themselves and to remember to sign the guest list before they leave the meeting. C. D. Taylor reported that guests will be given packets of materials so that they can follow meeting discussions. He requested that the guests please return the draft packets when they leave the meeting. D. Members of the Board with a conflict of interest relating to any item on the agenda were advised to notify the Board at this time or when the issue is addressed in the agenda. Introduction of pharmacy student on rotation with LaVerne Naesea at the Board: Mary Bales. E. Revisions to Minutes: Approval of April 21, 2009. 	Motion to accept minutes as amended: R. Matens Second: R. Zimmer	Board Action: The voted to approve the minutes as amended.

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II. Meeting Updates	Donald Taylor, Board President	A. Meeting Updates 1. R. Zimmer attended the ACPE Accreditation Review at the College of Notre Dame School of Pharmacy on April 27-29, 2010. He indicated that it was a very interesting and thorough process and that it appeared that the college would pass the second level of ACPE accreditation. 2. M. Handelman represented the Board at a meeting at OHCQ on bulk medications in Long Term Care on April 29, 2010. More information later.		
		3. L. Bradley-Baker attended the final APAP Coalition Meeting on May 12, 2010. Although the group will no longer meet, the Coalition's Facebook page will remain updated and active and any relevant information to the public regarding acetaminophen will be promoted through venues such as the Board of Pharmacy's booth at the annual Baltimore City Flower Mart.		
		4. L. Bradley-Baker attended the Drug Therapy Management (DTM) Committee Meeting on May 12, 2010. The committee is currently reviewing the protocols from People's Community Center and the University Maryland, College Park. The Board of Physicians wanted the committee to omitted some information that it felt was not necessary under, though it is required under current DTM regulations.		
		5. L. Bradley-Baker attended the Maryland Pharmacy Coalition (MPC) meeting on May 13, 2010. The new chair of the MPC for the upcoming year is Chi Wang (University of Maryland School of Pharmacy Student Government). A review of the past legislative session as well as plans for the upcoming session was discussed.		
		6. R. Zimmer attended the Howard County CERN meeting on May 13, 2010. Discussions included: a. BRAC effort to expand Ft. Meade and NSA facilities; and b. Presentation by John Reginaldi about the Nuclear Detection Program		
		7. Home Infusion Workgroup met on May 5, 2010. Cindy Anderson indicated that the group should complete their charge within two more meetings. The next meeting will be held June 2, 2010.		
		8. Institutional Workgroup met on May 6, 2010 Dave - comments? 9. The Board Staff Retreat was held on May 17-18, 2010 at the Maritime Institute.		

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		10. C. Anderson will be leaving tomorrow for a week working as a pharmacist in Haiti (from May 22-29, 2010).		
		11. The University of Maryland School of Pharmacy will hold their Honors Convocation ceremony on Friday May 21 st at 9:30 am at the Sheraton Baltimore City Center Hotel. Don Taylor will present the Pharmacist's Oath to the graduates.		
		12. NABP will hold its 106 th Annual Meeting in Anaheim on May 22-25, 2010. L. Israbian-Jamgochian has been awarded a travel grant by NABP to represent the Board. Lenna asked the Board's opinion on a National License administered through NABP. The majority of Board members were not in favor of a national license. The concept of national standards for pharmacy technicians was also discussed. The majority of the Board members were in favor of this concept.		
		13. There will be a conference at the Baltimore Intercontinental Harbor Court June 28-29, 2010 titled "Crossroads for Temperature Sensitive Drugs (USA)." K. France, Pharmacist Compliance Officer, will be a panel speaker. The agenda is still in the planning stage, but the topic is timely from the Board's perspective.		
		14. The MPhA's annual conference will be held in Ocean City at the Clarion Resort Fountainebleau Hotel June 12–15, 2010. The Board will host a booth at the event.		
		15. There will be a Summit for Healthcare Professionals held June 18, 2010 at the Turf Valley Resort in Ellicott City. The focus will be on "Caring for Service Members, Veterans and Their Families."		
		16. There will be a MPVC training at BWI Weston on June 22, 2010 for all professional volunteers.		
		17. Deputy Secretary Frances Phillips has asked Don Taylor to participate in a Mid-Atlantic Region H1N1 Summit on June 24, 2010 at The Marriott Inn and Conference Center in Hyattsville, Maryland. Maryland, Virginia, and DC State Health Officers, their staffs and partners from the neighboring states of Pennsylvania, Delaware and West Virginia are invited.		
		18. National Conference on Quality Health Care for Culturally Diverse Populations will be held on Oct 18-21, 2010 at the Baltimore Renaissance Harborplace Hotel. L. Bradley-Baker will be attending to represent the Board.		

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		19. NABP will be holding their District I and II Meeting in Cooperstown, NY October 29-31, 2010.		
		B. Introduction of Guest Presenter, Dr. Jennifer Thomas, who is the Project Manager of the Delmarva Foundation (Pharmacy Quality Improvement Community - PQIC).		
		Dr. Thomas gave an update on several medication safety projects. Two new potential areas of interest included oral anticoagulation and medication reconciliation.		
III. Executive Director	LaVerne	A. Staffing Updates: With the recent permanent hirings of a Pharmacist		
Director	Naesea, Executive	Compliance Manager and Public Information Officer, the Board is fully		
	Director	staffed with the exception of one inspector. The freeze exemptions to		
		hire a Help Desk and temporary employee for the Licensing Unit were		
		approved and the two seniors aides appointed from the Baltimore City		
		Health Department were all filled in May.		
		B. Maryland Pharmacy Laws Book: The Board was requested to	B. Motion: D.	B. Board Action:
		determine whether to continue amending to the State contract with	Chason.	The Board voted to
		Lexis/Nexis for the 2011 Lawbook or to consider issuing a bid in	Second: L. Israbian-	continue with Lexis/Nexis
		response to a request received from MPhA.	Jamogchian	contract.
		C. Legislation Affecting Board Budget: HB 114 - L. Bethman reported		
		that under HB 114, all Boards will be required to adopt sanctioning		
		guidelines, in addition to other requirements. The A.G's office is		
		working on a framework and set of general recommendations to assist		
		Boards in developing the guidelines.	D. Motion: D.	
		D. Receipt and Disposal of Prescription Medicationswhat was the	Chason Second: H. Finke	D. Board Action: Return letters to Practice Committee
		issue discussed?		1 ractice Committee
		E. Staff Retreat Summary: L. Naesea presented a summary of the staff		
		training meeting. Overall, it was a successful program.		

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		F. Nomination of Board Officers: LaVerne will collect nominations for		
		positions via email. Don recommended all Board members consider		
		1.		
		becoming an officer. Open nominations will be taken from the floor and the election conducted at the June 2010 board meeting.		
		3	Motion:	G. Board Action: No
		G. UK's Council for Healthcare Regulatory Excellence (CHRE) has	Second:	Action
		requested that the Board become a member by filling out a survey. We	Second:	Will be presented to
		would then have access to surveys filled out by other member nations		NABP by Lenna at
		(i.e., Australia, Canada, Denmark, Germany).		the upcoming NABP meeting.
IV. PEAC Report	Kathy Putz, PEAC	A. PEAC monthly statistics for the Board. See Attachment 1, Section D.		
V. Legislation and Régulations	Anna Jeffers, Legislation and Regulation Manager	A. Maryland Regulations - Status:		
		10.34.03 Inpatient Institutional Pharmacy		
		To be presented at the May Practice Committee Meeting		
		10.34.05, .07, .12, .13, and .15		
		Notice of Final Action published May 7, 2010 with an Effective Date of July 1, 2010.		
		NoFA 10.34.05,.07,.12,.13&.15 Md R. 050710		
		10.34.18 Continuing Education		
		Notice of Final Action published May 7, 2010 with an Effective Date of July 1, 2010.		
		NoFA 10.34.18 Md R 050710		
		10.34.20.0104 Format of Prescription Transmission		
		Proposal anticipated to be published June 4, 2010		

Subject	Responsible Party	Discussion	Motion	ACTION/RESULTS
		10.34.23 Pharmaceutical Services to Patients in Comprehensive Care		
		<u>Facilities</u>		
		Proposal anticipated to be published June 4, 2010		
		There was a brief discussion whether a Director of Pharmacy should be full time. The issue will be revisited when the Official Comments are considered		
		10.34.25 Delivery of Prescriptions		
		Proposal to be submitted to the Department of sign-off.		
		10.34.28 Automated Medication Systems		
		Published 12/04/10 Reproposal submitted to the Department April 12, 2010.		
		10.13.01 Dispensing of Prescription Drugs by a Licensee		
		Waiting to hear from Wendy Kronmiller LaVerne will make this a priority now that the staff training meeting is complete.		
		Pharmacist non-CLIA testing		
		No action, waiting on State laboratory to respond.		
VI. Inspection Program Report	Kimberly France, Compliance	A. Compliance monthly statistics for the Board. See Attachment 1, Section C.		
	Officer	B. A Draft Quality Assurance Peer Review Proposal was reviewed by Cynthia Anderson.		
		Refer to compliance for consideration on a case-by-case basis.		
VII. Management	LaVerne Naesea	A. MIS monthly statistics for the Board. See Attachment 1, Section F.		
Services		B. MIS Updates- new help desk person has installed new printers and computers and performed other tasks as assigned. The MIS Manager is please with his performance.		

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		C. Proposal for database system – The Board is awaiting an itemized bid from Systems Automation.		
VIII. Administration & Public Support	Patricia Gaither, Administration and Public Support Manage	A. Administration and Public Support monthly statistics for the Board. See Attachment 1, Section G. B. Staffing Updates		
IX. Public Relations Committee Report	Janet Seeds, Public Information Officer	A. Public Relations Committee Report: J. Seeds reported that the Board of Pharmacy booth was the first place winner at the annual Baltimore City Flower Mart. It was a very successful event. She also thanked all the staff and Board members who attended and worked the booth at the event. B. Acetaminophen Coalition Report: The coalition is formally dissolved as it has completed all of its stated goals to educate the public on the safe use of acetaminophen. The coalition will reconvene if the need arises. C. DTM Committee report. Motion to send a letter to the Board of Physicians proposing to work together to revise the current DTM regulations. D. Board's Emergency Preparedness Committee will hold a training and update meeting on November 21, 2010 at the BWI Weston. Attendees would include current volunteers and pharmacists, pharmacy technicians and those pharmacists, pharmacy technicians and pharmacy students who wish to become volunteers.	C. Motion: Lynette Bradley-Baker Second: Dave Chason	C. Board Action: The Board voted to approve the motion.
X. Practice Committee	Reid Zimmer, Chair Anna Jeffers, Legislation and Regulation Manager	Public Inquiries: 1) Jenny Harrison, Hills Pharmacy – verbal inquiry. Response to Jenny Harrison-Pharm Techs-RxDrugRep Program A repository shall designate a pharmacist who shall: (1) Accept donated prescription drugs or medical supplies forwarded by: (a) A drop-off site; or (b) A manufacturer regulated by the U.S. Food and Drug Administration. (2) Inspect donated prescription drugs or medical supplies;	1. Motion: Practice Committee Second: Dave Chason	1. Board Action: The Board voted to approve the motion.

Subject Responsible Party	Discussion	Motion	ACTION/RESULTS
(3) Accept donate requirements of R (4) Obliterate fror supplies patient spor medical supplie See COMAR 10.3 According to COI accepting donated may not delegate of medical supplie A registered pharminvolved in the druthe pharmacist, in "A repository shale compliance with a dispensing prescrition dispensing prescrition and prescrition are expirated by the pharmacist of the manufacture expiration date to wording on the primeeting the requirements of the pharmacist of the pha	d prescription drugs or medical supplies that meet the egulations .02 and .03 of this chapter; and in the labels of donated prescription drugs or medical secific information for which the donated prescription drugs is were originally dispensed when it is placed in inventory. 4.33.06B. MAR 10.34.33.05B, a pharmacist or health care practitioner prescription drugs or medical supplies at a drop-off site he initial step of acceptance of donated prescription drugs is. macy technician employed at a drop-off site may be op-off site process, after initial acceptance of the drugs by accordance with COMAR 10.34.33.07: I dispense donated prescription drugs or medical supplies in pplicable federal and State laws and regulations for ption drugs or medical supplies." Omnicare tion dates on labels see - Krusa – Omnicare gested amendments that are consistent with the following tacting the Maryland Board of Pharmacy requesting ding expiration date labeling requirements on pharmacy and "responsible pharmacist" duties of a Maryland of Below you will find responses to your inquiries.	2. Motion: Dave Chason Second: Harry Finke	2. Board Action: The Board voted to return to practice

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	. urty	Wording on the prescription label, such as "Exp. Date – see package" does		
		not suffice in meeting the requirements for determining the accurate		
		expiration date. The expiration date must appear on the prescription label.		
		Responsible pharmacist duties		
		Omnicare Inc. also requested clarification regarding the ability of a Maryland		
		licensed pharmacist to be designated as the responsible pharmacist for more		
		than one licensed pharmacy location in Maryland.		
		In a full service pharmacy "a pharmacist shall be immediately available on		
		the premises to provide pharmacy services at all times the pharmacy is in		
		operation." See COMAR 10.34.05.03A. If a pharmacist is full-time at one		
		pharmacy, that pharmacist may not be listed as full-time at another pharmacy		
		at the same time. If the pharmacist is listed as part-time at two pharmacies		
		then both pharmacies will have to list other pharmacists who will be working		
		when the pharmacist in charge is not available. The hours of operation and		
		the staffing of pharmacists must be consistent.		
		Whether or not a director of pharmacy at a comprehensive care facility may		
		be a director of pharmacy for more than one licensed pharmacy location at a		
		time is not currently addressed in COMAR 10.34.23 Pharmaceutical Services		
		to Residents in Long-Term Care Facilities. The Board is in the process of		
		revising COMAR 10.34.23 and this issue will be addressed after the		
		anticipated publication of those revisions in the Maryland Register on June 4,		
		2010. A 30 day comment period follows. Please refer to		
		www.dsd.state.md.us and click on "Maryland Register" on the left menu.		
		2) January Hayrana Arant Fay		
		3) Joanne Hawana,, Arent Fox	3. Motion: Practice Committee	3. Board Action: The Board voted to
		Pedigree Question Private Label Distributors	Second: Dave	approve the motion.
		Draft - Bd Response - Hawana - Arent Fox	Chason	
		The private label distributor you described in your e-mail would be required		
		to be licensed as a wholesale distributor in Maryland because, as you		
		indicated, it directs and controls the actual distribution of the product by the		
		third-party logistics provider. Forms are available on the Board's website at:		
		www.dhmh.maryland.gov/pharmacyboard		
		Pursuant to our phone conversations, your next concern was how a private		

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		label distributor would affect the normal distribution channel and who would provide the pedigree. The definition of normal distribution channel is narrow and is provided below:		
		(l) "Normal distribution channel" means a chain of custody for a		
		prescription drug that, directly or by drop shipment, goes:		
		(1) From:		
		(i) A manufacturer of the prescription drug; or		
		(ii) The manufacturer's co-licensed partner,		
		third party logistics provider, or manufacturer's exclusive distributor; and		
		(2) To:		
		(i) A pharmacy or other designated person		
		authorized by law to dispense or administer the prescription drug to a patient;		
		(ii) A wholesale distributor to a pharmacy or		
		other designated person authorized by law to dispense or administer the		
		prescription drug to a patient;		
		(iii) A wholesale distributor to a pharmacy		
		warehouse to the pharmacy warehouse's intracompany pharmacy or other		
		designated person authorized by law to dispense or administer the		
		prescription drug to a patient;		
		(iv) A pharmacy warehouse to the pharmacy		
		warehouse's intracompany pharmacy or other designated person authorized		
		by law to dispense or administer the prescription drug to a patient; or		
		(v) An authorized distributor of record to		
		another authorized distributor of record solely for distribution to an office-		
		based health care practitioner authorized by law to dispense or administer the		
		prescription drug to a patient. Health Occupations Article, 12-6C-01, Annotated Code of Maryland		
		The scenario described in your e-mail of April 1, 2010, is outside of the definition of normal distribution channel because the third party logistics provider distributes to other wholesale distributors, so it does not fall under 12-6C-01l(2)(v).		

Subject	Responsible Party	Discussion	Motion	ACTION/RESULTS
	,	Therefore, the private label distributor, of a prescription drug that leaves, or has ever left, the normal distribution channel shall provide, before each wholesale distribution of the prescription drugs, a pedigree to the person who receives the prescription drug. Health Occupations Article, 12-6C-10(a), Annotated Code of Maryland Since this is outside the normal distribution channel, the first authorized distributor of record would authenticate the pedigree as coming from the initial manufacturer. In your e-mail the first authorized distributor of record is the private label distributor who holds title to the product. 4) Doug Haggerty, Walgreens Haggarty - Schedule II prescription Draft - Bd Response - Haggerty - Walgreens	4. Motion: Practice Committee Second: Dave Chason	4. Board Action: The Board voted to return to Practice Committee
		S) Marianna F. Miyazaki, Arent Fox Vaccine distribution - Miyazaki - Arent Fox Draft - Bd Response - Miyazaki - Arent Fox Thank you for contacting the Maryland Board of Pharmacy concerning whether a company would need to be licensed by the Board if it purchases vaccines from a manufacturer/wholesale distributor for storage at one of the company's locations, and distributes to other of the company's locations, and then administered by a nurse pursuant to a physician's standing order. Please be advised that the company would have to be licensed as a wholesale distributor in Maryland in order for it to purchase vaccines and then distribute the vaccines to the physician/nurse. A nurse would administer the vaccines to individuals under the authority of the physician's license.	5. Motion: Practice Committee Second: Harry Finke	5. Board Action: The Board voted to approve the motion.

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VI Licensing	Mike Souranis,	A. Licensing Committee statistics for the Board.		
XI. Licensing Committee	Chair	See Attachment 1, Section A and E.		
		B. Letter for Out-if-State Wholesale Drug or Device Distributor Renewals	B. Motion: Licensing Committee made a motion to approve letter. Second: Harry Finke	B. Board Action: The Board voted to approve the motion.
		C. Approval of Repositories	C. Motion: Licensing Committee made a	C. Board Action: The Board voted to approve the motion.
		1. Halethorpe Pharmacy	motion to approve all 3 Repository	
		2. Joppa Road Pharmacy	applicants,	
		3. Independent Pharmacy	Second: Mayer Handelman	
XII. Disciplinary Committee	Lenna Israbian- Jamgochian, Chair	Compliance Committee monthly statistics for the Board. See Attachment 1, Section A and C.		
XIII. Long Term Care	Mayer Handelman, Chair	Committee Report Long Term Care letter should be drafted and sent to NABP for approval on controlled dangerous substance authority.	Motion: Mayer Handelmann Second: Harry Finke	Board Action: The Board voted to approve the motion.

Subject	Responsible	Disquesion	Motion	ACTION/RESULTS
XIV. Informational	Party Donald Taylor, President	Discussion A. FDA has initiated a new program "Bad Ad Program" where they are asking physicians to report ads and sales pitches that violate FDA rules. They are also offering physicians training at medical conferences (providing funding). There is NO mention of pharmacist participation. B. Tennessee allows vending machines in medical clinics. One company	A. Motion to send letter to FDA by Harry Finke Second: M. Souanis	A. Board Action: The Board voted to approve the motion.
		is installing Rx vending machines that dispense 60 different generics and can hold 1000 Rxs. Patients are given an ID # and can just pick up their medications on exit. The company states that they are not cutting out pharmacists, but are only dealing with acute medications and not chronic medications.		
		C. Pharmacists are increasingly finding a "changed profession." Not only is the job market becoming wobbly, but the skill-set required has shifted. They now need to know how to work in different environments (retail clinics, mail-order businesses, nursing homes, consulting). They must also be comfortable with new technology, drug therapy management, changing issues/regulations related to Medicare/Medicaid and the new politics of health care reform.		
		D. AMA Seeks Limits to Pharmacists Scope of Practice: 1. AMA is arguing that collaborative therapy has the potential to lead us to independent authority for pharmacists to monitor and modify medication therapy. 2. They have issued the "AMA Scope of Practice Data Series: Compendium on Pharmacists" which states among other things: a. Neither the Accreditation Council for Pharmacy Education nor state licensing requirements mandate direct patient contact		
		for student practice experience, and b. No evidence exists that the profession has modified the quality or manner in which students are trained to provide direct care to patients. 3. AMA introduced HR 2260 that would have required all health care providers (other than medical doctors or doctors of osteopathic medicine) to issue disclaimers informing patients that they do not have the skills and training of MDs and DO's. That bill did not make it out of committee, but they are now introducing similar bills at the state level (3 billsat this point),		

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XV.	Adjournment	Donald Taylor, Board President	A. D. Taylor asked for a motion to close the Public Meeting and open a Closed Public Session for the purpose of engaging in medical review committee deliberations of confidential matters contained in technician applications in accordance with State Government, Sect. 10-508(a)(13).	Motion: Richard Matens	The Public Meeting was adjourned at 11:48 am.
				Second: Dave Chason	